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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/289,044	04/09/1999	ANDREW H. SOLL	1726-001	8196
9629 7590 05/17/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER RIMELL, SAMUEL G	
			ART UNIT 2164	PAPER NUMBER
			MAIL DATE 05/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/289,044

Applicant(s)

SOLL ET AL.

Examiner

Sam Rimell

Art Unit

2164

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/21/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following quoted statements are not recited in the original disclosure.

Claim 74: “prioritize said patient’s major complaints”, “major complaints are ranked by relevance”, “interview configuration profile”, and “configuration profile”.

Claim 75: “index symptom”, “index symptoms”, “redundant characterization of detail is skipped”.

Claim 76: “functional status”, “concurrent symptom groups”.

Claim 77: “functional status”, “generic domains”.

Claim 78: “functional status”.

Claim 80: “Individual scores are reported to facilitate interpretation by a physician”.

Claim 81: “automate patient recruitment for research trials”, “query patients”, “receive eligibility requirements for research studies”, “qualify patients for a research study”, “inform a patient and a research coordinator of studies for which said patient is eligible”.

Remarks

Applicant's arguments have been considered. However, the arguments do not overcome most of the applied rejections, for the following reasons. Points where the rejection is overcome are also noted.

Claim 74: The "prioritization of patient complaints" is described as being a triage, described at pages 36-37 of applicant's specification. However, the claim language in claim 74 suggests prioritization being performed by the data processing system itself. The discussion at pages 36-37 only refer to the patient inputting symptom information. No discussion appears at this point indicating what the processor systems does with this information, or the processor outputting any manner of data indicating prioritization. While the discussion does outline a nurse giving priority action to a patient having symptoms, there is no indication of the processing system creating any manner of prioritization data or of outputting such prioritization data.

For "major complaints ranked by relevance", applicants points to block 815. This block says "establish priority to patient" and makes no mention of ranking anything. Page 90, line 10 does mention "presenting problems in order of greatest concern", which does suggest some manner or ranking, but it is not a ranking by "relevance", using the relevance criteria set forth in claim 74 at lines 10-12.

For "interview configuration profile", applicant initially relies on the claim itself. However since claim 74 is not part of the originally filed disclosure, the claim itself provides no evidence to support the conclusion that it is part of the original disclosure. Applicant also quotes from pages 29, 31, 81, 82, and 83. None of these quotations make any reference to an interview configuration profile, or any manner of profile.

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Claim 75: For “index symptom”, applicant refers to the term “index complaint” at page 43. However, a complaint and a symptom are not physically the same thing. A complaint is what is verbally described whereas a symptom is a physiological problem.

For “redundant characterization of detail is skipped”, applicant refers to quotations at pages 43, 44, and 56. None of these quotations refer to the action of skipping over steps due to redundant details. The branching actions described are not due to redundancies being detected in the information.

The “risk of frustrating” is addressed in the specification, and rejection of this term withdrawn.

Claim 76: For “functional status”, applicant quotes from 21, 63 and 64. None of these quotations refer to functional status. “Level of functioning” and “functional impact” do not define a “functional status”.

For “concurrent symptom groups”, applicant quotes from pages 55, 56 and 57. None of these quotations describe “concurrent symptom groups”. The term “concurrent”, as best as can be understood, implies information which occurs and exists at the same point in time. The “overlapping” described in the specification at page 57 appears to be referring to multiple symptoms which are merely similar, not symptoms which are co-existing at the same point in time.

For “separate scores calculated for of said symptom groups”, applicant has demonstrated where the feature was originally disclosed and the rejection withdrawn.

Claim 77: For “functional status”, applicant quotes from 21, 63 and 64. None of these quotations refer to functional status. “Level of functioning” and “functional impact” do not define a “functional status”.

For “generic domains”, applicant quotes from pages 21 and 63. While reference is made to “domains”, it is not clear what constitutes a “generic domain”.

Claim 78: For “functional status”, applicant quotes from 21, 63 and 64. None of these quotations refer to functional status. “Level of functioning” and “functional impact” do not define a “functional status”.

Claim 80: For “different levels of severity are assigned different scores”, this rejection has been overcome by the amendment accompanying the response.

For “individual scores are reported to facilitate interpretation by a physician”, applicant quotes from pages 12, 17, 21, 25, 39, 51 and 64. None of the quotations make any reference to reporting individual scores to a physician.

Claim 81: For “automate patient recruitment for research trials”, applicant refers to page 41. These quotations do make reference to automating the informed consent process, but not of automating patient recruitment. As understood, the term “recruitment” means finding and locating participants, not merely seeking the consent of those already recruited.

For “query patients”, applicant refers again to page 41, describing the informed consent process”. The term “query” used in claim 81 refers to questioning the patient as to whether they wish to receive information on multiple research studies, not questioning as to whether they provide consent to participate in a study. The particular query questions being described in the claim are not set forth in this quotation.

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For “receive eligibility requirements” and “qualify patients for a research study”, applicant argues that these are inherent features to “the new paradigm” for informed consent, although no evidence is provided that applicant intended for these steps to be followed during the informed consent procedure described in the specification.

This office action follows the filing of an RCE request and is made non-final.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (571) 272-4084.



Sam Rimell
Primary Examiner
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